

27. (New) An IGF composition wherein the overall purity of the IGF obtained is about 95-97%.

28. (New) A process for purifying IGF-I comprising loading a mixture containing IGF-I onto a preparative reversed-phase liquid chromatography column and eluting the IGF-I from the column with a buffer at a pH of about 6-8 containing an alcoholic or polar aprotic solvent at a concentration of about 20-30% (v/v).

29. (New) The process of claim 28 wherein the column is packed with a medium having a particle diameter of about 5-40  $\mu\text{m}$ , a pore size of about 100-4000 Å and a C4, C8, or C18 alkyl group.

30. (New) The process of claim 28 wherein the medium has a particle diameter of about 10-15  $\mu\text{m}$  and a pore size of about 150-300 Å, and is a C4 silica medium.

31. (New) The process of claim 28 wherein the mixture is loaded in about 5-20% (v/v) of an alcoholic or polar aprotic solvent.

32. (New) The process of claim 28 wherein the level of IGF-I loaded is about 0.02 to 30 mg IGF-I/mL bed volume.

33. (New) The process of claim 28 wherein sodium chloride or potassium chloride is also present in the buffer at a concentration of from about 10 mM to the solubility limit of the sodium chloride or potassium chloride.

34. (New) The process of claim 28 wherein the buffer is a phosphate buffer in which the phosphate is at a

concentration from about 10 mM to the solubility limit of the phosphate.

35. (New) The process of claim 34 wherein the phosphate buffer is at a concentration of about 10-200 mM.

36. (New) The process of claim 34 wherein the phosphate buffer is about 100 mM sodium or potassium phosphate, pH adjusted to about 7.

37. (New) The process of claim 28 wherein the solvent is acetonitrile.

38. (New) The process of claim 28 further comprising loading the IGF-I containing eluate onto a cation-exchange column and eluting the IGF-I.

39. (New) The process of claim 38 wherein the IGF-I-containing eluate from the cation-exchange column is desalted and diafiltered or gel filtered.

40. (New) An IGF-I composition prepared by the process of claim 39 comprising a pharmaceutically acceptable carrier.

41. (New) A process for purifying IGF-I comprising:

- (a) loading a buffer containing IGF-I at a pH of about 3-8 onto a hydrophobic interaction chromatography column;
- (b) washing the column with a buffer at a pH of about 3-8;
- (c) eluting the IGF-I with a buffer at a pH of about 3-8;

(d) loading the IGF-I containing eluant onto a preparative reversed-phase liquid chromatography column; and

(e) eluting the IGF-I from the reversed-phase liquid chromatography column with a buffer at a pH of about 6-8 containing an alcoholic or polar aprotic solvent at a concentration of about 20-30% (v/v).

42. (New) The process of claim 41 wherein the hydrophobic interaction chromatography column is a phenyl column.

43. (New) The process of claim 41 wherein the pH of the buffer in steps (a) to (c) is about 3-4.

44. (New) The process of claim 41 wherein the buffers for steps (a)-(c) are a citrate or ammonium buffer or both at pH about 6-8.

45. (New) The process of claim 44 wherein the buffers for steps (a)-(c) are 0.1-1 mM ammonium sulfate or ammonium citrate.

46. (New) The process of claim 41 wherein the buffer for step (e) is a phosphate buffer consisting of about 100 mM sodium or potassium phosphate, pH adjusted to about 7 and the solvent for step (e) is acetonitrile.--

#### Remarks

New claims 25-27 are directed to additional embodiments of the invention. In particular, these claims recite the overall purity of IGF compositions according to the invention. Support for these claims can be found throughout the specification at, *inter alia*, page 32, lines 20-21.